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EXAMINER

ATZEL, A

ART UNIT

PAPER NUMBER

1807

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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DETAILED ACTION

Compliance with Sequence Rules is acknowledged.

The listing of references in the specification on pages 106-116 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

*Drawings*

The drawings are objected to for reason set forth in form PTO-948. Submission of corrected drawings can be deferred until allowable subject matter is indicated by the examiner.

*Claim Rejections - 35 USC § 112*

Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 7, the meaning of "standard hybridization conditions" is unclear because there is no such thing as "standard" hybridization conditions. It is suggested that temperature and salt concentrations be indicated.

The preamble to claim 14 should read "A method of making MTAP protein comprising" or something similar.

In claim 36, the meaning of "T98G" is unclear in that no specific characteristics of the claimed chemical are given besides that it is DNA.

*Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 34 and 35 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter. These claims read on all endogenous tumor suppressor genes on chromosome

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9p21-22. Non-isolated products of nature are non-statutory subject matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34 and 35 are rejected under 35 USC § 102(b) as being anticipated by Serrano et al. (1993) or by Kamb et al. (1994). Serrano et al. disclose p16INK4, and Kamb et al. disclose MTS1, both of which are tumor suppressor genes that map to 9p21-22.

Claims 34-38 are rejected under 35 USC § 102(a) as being clearly anticipated by Porterfield et al. (1994). Porterfield et al. disclose a tumor suppressor gene that maps to chromosome 9p21, and methods of distinguishing tumor types by comparing 9p deletions between tumors identical to the claimed invention.

Claims 34-38 are rejected under 35 USC § 102(b) as being clearly anticipated by Porterfield et al. (1992) or by Cheng et al. (1994). Both references disclose a tumor suppressor gene that maps to chromosome 9p21, and methods of distinguishing tumor types by comparing 9p deletions between tumors identical to the claimed invention.

Claims 26-33 are rejected under 35 USC § 102(b) as being clearly anticipated by Nobori et al. (Cancer Res. 1991) or by Nobori et al. (Cancer Res. 1993). Nobori et al. disclose methods, kits and antibodies that bind to MTAP that are linked to alkaline phosphatase through a secondary antibody (Nobori et al., 1991) or linked to an I-125 label via protein A.

Claims 1-12, 15-18, 20-25, 34-38 are rejected under 35 USC § 102(b) as being clearly anticipated by Nobori et al. (Nature 1994). Nobori et al. disclose MTAP cDNA, gene and isolated region designated T98G, and kits and methods of use.

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Claims 1-12, 15-18, 20-25, 34-38 are rejected under 35 USC § 102(b) as being clearly anticipated by Bohlander et al. (1994). Bohlander discloses a chromosome fragment comprising the MTAP gene, kits and methods of use identical to the claimed invention

Claims 1-12, 15-18, 20-25, 34-38 are rejected under 35 USC § 102(a) as being clearly anticipated by Dreyling et al. (Cancer Res. 1995). Dreyling et al. disclose DNA segments comprising the MTAP gene and isolated region designated T98G, and kits and methods of use. See figure 1.

Claims 1-13, 15-25, 34, 35, 37, 38 are rejected under 35 USC § 102(a) as being clearly anticipated by Olopade et al. (PNAS 1995). Olopade et al. disclose MTAP cDNA, gene and isolated region designated T98G, and kits and methods of use including Northern blots.

Claims 37 and 38 are rejected under 35 USC § 102(b) as being clearly anticipated by Scaletti et al. (1987). Scaletti et al. disclose methods of distinguishing tumor types by comparing chromosome 9p patterns between tumor types.

Claims 1, 5 and 6 are rejected under 35 USC § 102(b) as being anticipated by Chakraborti and Kozak (1992). This reference discloses genes encoding microtubule associated proteins known as MTAP.

Claims 13 and 14 are rejected under 35 USC § 102(b) as being anticipated by Coffey et al. (1994). This reference discloses expression of microtubule associated proteins (MTAP) in bacteria as well as purification of the expressed product to homogeneity.

#### **Conclusion**

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If attempts to contact the examiner are unsuccessful please call Supervisory Patent Examiner Gary Jones at (703) 308-1152.

Amy Atzel, Ph.D.  
February 18, 1997

  
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SUPERVISORY PATENT EXAMINER  
GROUP 1800

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